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Association

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Food and Drug Administration
5630 Fishers Lane
Room 1061
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RE: Docket No. 02N-0276
Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

The National Grain and Feed Association (NGFA) and the North American Export Grain Association (NAEGA) submit this joint statement in response to the Food and Drug Administration's notice of proposed rulemaking that would require domestic and foreign facilities that manufacture, process, pack or hold food for human or animal consumption in the United States to register with the agency by December 12, 2003. The FDA-proposed regulations are intended to implement portions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 [Bioterrorism Act].

The NGFA, established in 1896, consists of 1,000 member companies from all sectors of the grain, feed, processing and exporting business that operate about 5,000 facilities that handle more than two-thirds of all U.S. grains and oilseeds. The NGFA's membership includes country, terminal and export elevators; feed manufacturers; cash grain and feed merchants; end users of grain and grain products, including processors, flour millers, and livestock and poultry integrators; commodity futures brokers and commission merchants; and allied industries. The NGFA also consists of 36 affiliated state and regional grain and feed associations, as well as two international affiliated associations. The NGFA also has established strategic alliances with the Pet Food Institute and the Grain Elevator and Processing Society.

NAEGA, established in 1912, is comprised of private and publicly owned companies and farmer-owned cooperatives involved in and providing services to the bulk grain and oilseed exporting industry. NAEGA member companies ship practically all of the bulk grains and oilseeds exported each year from the United States. The Association's mission is to promote and sustain the development of commercial export of grain and oilseed trade from the United States. NAEGA acts to accomplish this mission from its office in Washington D.C., and in markets throughout the world.

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The NGFA and NAEGA are committed to enhancing the security of U.S. agricultural facilities and support reasonable, prudent steps that enable FDA to better respond promptly and effectively to a threatened or actual terrorist attack on the U.S. food or feed supply, without imposing undue burdens or costs on the food and feed system. As a demonstration of this commitment, the NGFA on November 16, 2001 published an ***Agribusiness Facility and Operations Security*** guide that outlines security issues and considerations that may need to be addressed at agribusinesses. The guide includes sections on conducting a facility vulnerability assessment; improving the general security of the physical facility and grounds; implementing prudent security operating, shipping and receiving procedures; and a sample emergency action plan. The guide has been distributed widely by the NGFA, and is available at no charge to members and nonmembers alike.

The NGFA and NAEGA offer the following comments concerning specific aspects of FDA's proposed rules for registration of domestic and foreign facilities that manufacture, process, pack or hold food for human or animal consumption:

- **Section 1.227(c)(2) – Facility:** FDA proposes to define "facility" as "any establishment, structure or structures under one management at one general physical location, or, in the case of a **mobile facility**, traveling to multiple locations, that manufactures/processes, packs or holds food for consumption in the United States." *[Emphasis added.]* The NGFA and NAEGA encourage FDA to clarify whether the definition of mobile facility includes so-called domestic "trucker-dealers" who typically do not operate stationary warehouse facilities, but purchase and take title to grain from producers and "hold" grain in a conveyance for subsequent transport to another agricultural storage facility, miller, processor or end user. Clarification also is requested as to whether FDA considers domestic or foreign transport conveyances – such as railcars, barges, trucks or vessels – that transport food or feed to be "mobile facilities" subject to the registration requirement.

  Further, the NGFA and NAEGA believe that FDA should modify this section of its proposed rules to clarify that domestic grain-handling, feed manufacturing/ingredient or processing facilities dedicated solely to exporting bulk or processed agricultural commodities to other countries should be **exempt** from the registration requirement unless the commodities, products or byproducts they handle are introduced into U.S. commerce. This clarification would be consistent with the statutory language and FDA's proposed regulations that the registration requirement applies only to domestic and foreign facilities that manufacture, process, pack or hold food for human or animal consumption in the United States.

- **Section 1.227(c)(3) – Farm:** Under the Bioterrorism Act, "farms" are exempt from the registration requirement. FDA proposes to define farm as a "...facility in one general physical location devoted to the growing of crops for food, the **raising of animals for food** (including seafood), or both...." *[Emphasis added.]* In the narrative preceding the proposed rule, FDA clarifies that "some examples of farms" include "...hog farms, dairy farms, feedlots, or aquaculture facilities." FDA further clarifies that the "definition of farm does not include facilities that contract with multiple farmers to grow crops or raise animals." The NGFA and NAEGA believe FDA's definition of the "farm" exemption should be size-neutral, and apply equally to integrated livestock and poultry facilities, so long as the activities engaged in at such locations are limited to "growing or raising" farm animals for human food but do not extend to further processing of food-producing animals into meat, milk or eggs (such as occurs at food processing and packing plants and rendering facilities) for subsequent commercial sale to humans or animals.

- **Section 1.227(c)(11) – Retail Facility:** The Bioterrorism Act specifically exempts "retail food establishments" from the registration requirement. Consistent with the definition of "food" contained in Section 201(f) of the Federal Food, Drug and Cosmetic Act [which states, in relevant part, *"...articles used for food or drink for man or other animals...,"]* as well as the definition of "food" being proposed by FDA in Section 1.227(c)(4) of the regulations [which includes *"animal feed, including pet food, food and feed ingredients and additives"*], the NGFA and NAEGA believe FDA should interpret the exemption to also apply to retail facilities – such as retail farm supply and feed stores – that are not engaged in manufacturing animal feed, pet food or feed ingredients or additives, but whose activities are confined to the retail sale of bulk or bagged animal feed, pet food or feed ingredients/additives directly to customers and consumers.

- **Section 1.231 – Procedures for Registration:** The NGFA and NAEGA commend FDA for encouraging electronic registration, and for not charging a fee for registration. We also commend FDA for permitting companies with multiple facilities the option of filing registration forms on behalf of one or more of their facilities. However, FDA's proposal to require that affected companies complete individual registration forms – in either electronic or paper format – for each of their facilities will be a time-consuming and laborious process. The NGFA and NAEGA encourage FDA to explore ways in which data required by the agency as part of the registration form could be made available by companies with multiple facilities in a standardized computer format rather than requiring manual entry of individual facility data on each subsequent registration form.

FDA also notes that a facility will be considered to be registered when the agency assigns a facility-specific registration number. For registration by mail, we commend FDA for providing that it will return the registration form to the potential registrant if it contains incomplete or illegible information. However, it is not clear in this section of the proposed regulations that FDA will provide similar notification to those registering electronically. Therefore, the NGFA and NAEGA encourage FDA to add a provision to Section 1.231(a) stating that those registering electronically will be notified with an electronic prompt or error message if the registration has not been accepted, as well as the reason for the error (such as a missing field of required information). This would avoid a situation in which a party registering electronically presumes the registration is effective, even though the facility has not been assigned a registration number.

- **Section 1.232 – Required Registration Information:** FDA proposes to utilize its product code builder categories as the required fields in Section 11 of its draft Food Facility Registration Form for identifying "any food" that is manufactured, processed, packed or held at a facility. Since this is a statutory requirement, the NGFA and NAEGA do not object to the use of the product code builder categories for this purpose, although we do note that these category descriptions are not well known to our industry. We do recommend that the explanatory language of Section 11 of the draft registration form be amended to extend the underscored portion to also apply to the phrase "except those that are solely warehouses [underscore added]." Doing so would help clarify that item number 36 ["whole grains, miller grain products (flours) or starch) is **not** to be checked if the facility is engaged only in raw grain storage or handling operations.

  In a broader context, the NGFA and NAEGA are concerned that the structure and organization of the draft Food Facility Registration Form published in the March 6, 2003 ***Federal Register*** will cause confusion as to which information is required by law – and subsequently subject to updating if changes occur – versus information that is optional and is to be provided at the discretion of the registrant. While we recognize that the optional sections of the form are designated as such, those sections are interspersed with sections where information is required to be submitted by the registrant. For instance, Sections 1, 2, 4, 5, 6, 7, 11 and 12 of the form contain references to information that is required under the Bioterrorism Act (e.g., the name and address of each applicable facility, all trade names, and general food categories defined under 21 CFR 170.3). Meanwhile, interspersed among the aforementioned sections of the form are Sections 3, 8, 9, 10 and 11a, which contain references to information that is optional.

At a minimum, the NGFA and NAEGA recommend that FDA insert the word "**REQUIRED:**" in boldfaced, underscored and all capital letters following the section titles to clarify further which information the registrant is required to submit and to update within 30 days after changes occur. Similarly, to enhance clarity, we recommend that insertion of the term "**OPTIONAL**" where found in the current draft form also should be relocated to immediately follow the section title. Examples of our recommended changes would include:

"Section 2 – FACILITY NAME/ADDRESS INFORMATION (REQUIRED)

Section 3 – ~~OPTIONAL: –~~PREFERRED MAILING ADDRESS INFORMATION (OPTIONAL)

We also recommend that instructions be provided for filling out the form that include specific citations to those sections where the information is required and those that are optional.

In addition, the NGFA and NAEGA commend FDA for allowing parent corporations to list as the emergency contact the name of the individual at the company's headquarters who has overall corporate responsibility for responding to emergencies that may occur at any of the facilities owned and/or operated by the parent company, rather than requiring a separate local contact at each facility. This will facilitate an expeditious and effective systemwide response by larger companies to any alerts they may receive from FDA concerning alleged threats to the safety or security of the food supply.

Section 1.234 -- Updating Registration Information and Canceling Registration: FDA proposes to require that the owner, operator or agent in charge of a facility update **any information** – including optional information – previously provided on the registration form within 30 days of any changes. We understand the agency's desire to have current information on file to conform to the purposes outlined in the Bioterrorism Act. However, the NGFA and NAEGA believe that a registrant's failure to update optional information (such as the type of activities conducted at the facility, as well as the food categories or type of storage) should **not** be considered to be a "prohibited act" under Section 301 of the Act, which subjects the offending registrant to potential civil and criminal penalties. Therefore, we urge FDA to state in its final regulations that while updating optional information – if initially provided by the registrant – is desired, failure to do so will **not** subject the registrant to penalties under the Act or FDA's implementing regulations. We believe that failure to do so could have a chilling effect on the willingness of companies to provide the optional information in the first place.

In addition, FDA proposes to require that a facility cancel its registration, presumably if it no longer is engaged in activities that subject it to the requirements of the act or implementing regulations. However, FDA does not state in its proposed regulations the conditions or circumstances under which a cancellation notice is required. The NGFA and NAEGA urge FDA to add language in its proposed regulations to clarify the circumstances under which a cancellation notice is required (e.g., the facility no longer is operational; the facility has been sold to another party; the facility no longer manufactures/ processes, packs or holds "food articles" subject to the provisions of the Bioterrorism Act, etc.).

We also believe that the amount of information FDA proposes to require in the cancellation notice is excessive. Since FDA proposes to assign each facility a unique registration number, it would appear that providing the facility's registration number, the name and contact information for the person submitting the cancellation, and the certification statement would suffice for the purposes of a cancellation notice. Under this recommendation, the facility's name and address and whether it is a domestic or foreign facility would be not be required in a cancellation notice, since this information already would have been captured by FDA as part of the registration.

Further, FDA may wish to consider specifying a time by which the registrant is required to provide cancellation notification to the agency. We do not believe that the same 30-day deadline applicable to updates in the registration form is appropriate for cancellation notices, particularly given the volume of activity that may be associated with the sale or transfer of a facility to new ownership. Instead, we suggest that a 90- to 120-day time frame may be more appropriate for the registrant to provide such a cancellation notice.

- **Section 1.241 – Failure to Register:** Under the Bioterrorism Act and this section of FDA's proposed regulations, failure to register is a prohibited act and subjects the offending party to civil and criminal penalties, as well as debarment. Further, this section of the proposed rule delineates the dire and costly consequences if an article of food is offered for import and a foreign facility that manufactured/processed, packed or held the food has not registered or whose registration is not in order. These penalties include holding the product at the port of entry or diverting the article of food to a U.S. Customs Service bonded warehouse or other FDA-approved secure facility, with transportation and storage costs to be borne by the "owner, purchaser, importer or consignee." Alarmingly, FDA proposes to hold the "person who imports or offers for import" financially liable for these costs and disruptions if the foreign facility is not registered.

The NGFA and NAEGA strongly object to placing on the importer the financial liability and burden associated with a foreign facility's failure to register. No such obligation is placed on the importer in the Bioterrorism Act itself. Instead, 21 U.S.C. 381 places the responsibility for registering foreign facilities squarely on "the owner, operator or agent in charge" of that facility. That is where the liability should be placed with respect to imported food articles if the registration is not in order when food articles are imported or offered for import to the United States. We believe doing otherwise contradicts the intent of the statute, is impractical and places undue financial liability on the importer. We also encourage FDA to continue its proactive efforts to inform regulated facilities, particularly those in foreign countries, of their obligations to register under the Bioterrorism Act.

FDA also requests comments on the circumstances under which a firm's registration should be considered null-and-void, as well as the circumstances under which a firm's registration should be revoked. The NGFA and NAEGA urge FDA to proceed cautiously on this aspect of its proposed rules. We believe that registrations should be considered null-and-void or be subject to revocation only if it involves required information that is of a material nature that is knowingly untruthful, fictitious or fraudulent, and is of sufficient gravity to undermine FDA's ability to implement its responsibilities under the Bioterrorism Act. Further, FDA should **not** use suspension or revocation of a facility registration as an additional enforcement tool for alleged violations of other agency regulations that are outside the scope of the Bioterrorism Act.

- **Section 1243 – Public Availability of Registration Information:** The Bioterrorism Act wisely provides that a list of registrants "and any registration documents submitted...shall not be subject to disclosure..." under the Freedom of Information Act [5 U.S.C. 552] "to the extent that it discloses the identity or location of a specific registered person." The intent of such an exclusion is to avoid providing a "road map" to potential terrorists who might seek to compromise the safety of the U.S. food and feed supply. The NGFA and NAEGA commend FDA for codifying this exemption in its proposed regulations. However, we believe that FDA should clarify its proposed regulation by expressly stating that this exemption from Freedom of Information Act disclosure also applies to facility-specific information provided by the registrant, not just to the forms themselves and the "identity or location of the specific registered person."

  In this regard, the NGFA and NAEGA propose that this section of the proposed regulations be reworded as follows *[New language boldfaced and underscored, deleted language stricken through]*:

*"(a) **Company- or facility-specific information contained in** ~~R~~registration forms submitted under this subpart, and any information contained in those forms that would disclose the identity or location of a specific registered person **or facility** is not subject to disclosure under 5 U.S.C. 552 (the Freedom of Information Act)."*

The NGFA and NAEGA appreciate this opportunity to provide our collective input on FDA's proposed regulations to implement the registration requirements of the Bioterrorism Act. We believe our proposed changes will contribute to implementing the law in the most efficient manner possible, while minimizing the regulatory burdens and costs that could disrupt efficient business operations by companies engaged in providing an abundant and affordable food supply to U.S. and world consumers.

We pledge our continued proactive efforts to work with our industry sectors and with government to further enhance the safety and security of the nation's food and feed supply.

Sincerely,

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